

PATENT
Customer No. 22,852
Attorney Docket No. 09481.0009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
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Jeffrey A. HEROUX <i>et al.</i>)	Group Art Unit: 1637
)	
Serial No.: 09/976,437)	Examiner: S. Chunduru
)	
Filed: October 15, 2001)	
)	
For: ASSAYS FOR MEASURING)	
NUCLEIC ACID BINDING)	
PROTEINS AND ENZYME)	
ACTIVITIES)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

Applicants now respond to the Office Action mailed February 24, 2004.

Applicants would like to thank Examiner Chunduru for extending the courtesy of a telephonic interview to discuss the descriptions of Groups I and II in the Office Action (restriction requirement). In the Office Action, the Examiner required restriction under 35 U.S.C. § 121 between the following allegedly patentably distinct groups of claims:

I. Claims 45-69, drawn to a method of assaying a sample for an activity relating to nucleic acids, classified in class 435, subclass 6.

II. Claims 45-76, drawn to a method of assaying a sample for an activity relating to peptides, and enzymes, classified in class 435, subclass 7.1.

III. Claims 77-80, drawn to a kit for measuring the activity of an enzyme, classified in class 536, subclass 22.1.

Applicants elect, with traverse, the subject matter of Group 2 based on the understanding from the telephonic interview that "assaying a sample for an activity relating to peptides, and enzymes" means "assaying a sample for an activity catalyzed by a peptide(s) or an enzyme(s)." Similarly from the telephonic interview, Applicants understand "assaying a sample for an activity relating to nucleic acids" in Group 1 to mean "assaying a sample for an activity catalyzed by a nucleic acid." If Applicants' understanding of the restriction requirement is incorrect, the Examiner is requested to further clarify the restriction requirement and to afford Applicants an opportunity to revise their election.

Applicants respectfully traverse the restriction requirement. Applicants respectfully submit that the allegedly patentably distinct Groups I, II and III in fact form a single Group.

MPEP § 803 dictates that

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i); and


(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).

Applicants submit that the distinct Group I and Group II are in fact related inventions. They are related by the essence of the invention - an assay utilizing

electrochemiluminescence. Regardless of whether the catalytic activity stems from a proteinaceous or nucleic acid molecule the claimed assays utilize the electrochemiluminescent method. For example, an assay might seek materials capable of cleaving a nucleic acid tethered to the solid support with a distal chemiluminescent label. *A priori*, whether the enzyme activity stems from a proteinaceous or nucleic acid source need not be known in order to perform the assay. The claimed assay could be used to detect the presence of either a proteinaceous or nucleic acid enzyme or both.

Applicants further note that both subclass 6 (Involving Nucleic Acid) and subclass 7.1 (Involving Antigen-Antibody Binding, Specific Binding Protein Assay, or Specific Ligand-Receptor Binding Assay) fall as single-dot subclasses under subclass 4 (Measuring or Testing Process Involving Enzymes or Microorganisms; Composition or Test Strip Therefore; Process of Forming Such Composition or Test Strip) in class 435. Applicants submit that the inventions of Groups I and II are in fact related and best classified under subclass 4 of class 435. As both subclasses 6 and 7.1 fall within subclass 4 maintaining the invention as claimed in a single application does not impose a serious burden on the Examiner.

Applicants submit that the inventions of Groups I and III have a disclosed relationship namely as a process (method of Group I) and an apparatus (kit of Group III) capable of being used in practicing the process. See MPEP § 802.01. The MPEP defines the term “independent” to mean that “there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed; or (2) process and apparatus incapable of being used in practicing the



process.” See MPEP § 802.01. Here, the kit of Group III is capable of being used in practicing the process of Group I. In fact, the Examiner points to no other use for the kits of Group III and fails to provide an explanation for how the inventions are unrelated.

Similarly, Applicants submit that the inventions of Groups II and III have a disclosed relationship namely as a process (method of Group II) and an apparatus (kit of Group III) capable of being used in practicing the process. As above, the kit of Group III certain is capable of being used in practicing the process of Group II. See MPEP § 802.01. Thus, the inventions of Groups II and III are not independent and should be examined together.

Moreover, MPEP § 803 requires “a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).” See MPEP § 803. Given that both subclass 6 (Involving Nucleic Acid) and subclass 7.1 (Involving Antigen-Antibody Binding, Specific Binding Protein Assay, or Specific Ligand-Receptor Binding Assay) fall as single-dot subclasses under subclass 4 and that the claimed assay could be used to detect the presence of either a proteinaceous or nucleic acid enzyme or both, no serious burden exists.


For the reasons above, Applicants respectfully request the reconsideration and withdrawal of the restriction requirement.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: May 24, 2004

By: 
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